IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS

RHONDA GENTRY, Plaintiff, vs. ICU MEDICAL, INC. Defendant.	Case No.: 5:24-cv-01062 **FIRST AMENDED COMPLAINT FOR DAMAGES** **(1) NEGLIGENCE** **(2) DESIGN DEFECT** **(3) FAILURE TO WARN** **(4) BREACH OF IMPLIED WARRANTY** **(5) BREACH OF EXPRESS WARRANTY** **(6) FRAUDULENT CONCEALMENT** **(7) TEXAS'S DECEPTIVE TRADE PRACTICES-CONSUMER PROTECTION ACT** **DEMAND FOR JURY TRIAL**

SECOND AMENDED COMPLAINT

COMES NOW Plaintiff, Rhonda Gentry, (hereinafter "Plaintiff"), by and through her undersigned counsel, and brings this Second Amended Complaint against ICU Medical, Inc, (the "Defendant"), and alleges as follows:

1. This is an action for damages arising out of failures relating to Defendant's design, development, testing, assembling, manufacturing, packaging, promoting, marketing, distribution, supplying, and/or selling the defective implantable vascular access device sold under the trade name of Port-A-Cath II (hereinafter "Port-A-Cath II" or "Defective Device").

PARTIES

2. Plaintiff, Rhonda Gentry is an adult resident and citizen of Bexar County, Texas, and claims damages as set forth below.

3. On information and belief, ICU Medical, Inc. is a corporation organized under the laws of the State of Delaware and has a principal place of business at 951 Calle Amanecer San Clemente, CA 92673 is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the Port-a-Cath II.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and cost.

5. Venue is proper in this Court pursuant to 28 U.S.C. §1391 by virtue of the facts that (a) a substantial part of the events or omissions giving rise to the claims occurred in this District, and (b) Defendant's products are produced, sold to, and consumed by individuals in the State of Texas, thereby subjecting Defendant to personal jurisdiction in this action and making them all "residents" of this judicial District.

6. Defendant has and continues to conduct substantial business in the State of Texas and in this District, distribute vascular access products in this District, receive substantial compensation and profits from sales of vascular access products in this District, and made material omissions and misrepresentations and breaches of warranties in this District, so as to subject them to *in personam* jurisdiction in this District.

7. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendant because Defendant is present in the State

of Texas, such that requiring an appearance does not offend traditional notices of fair and substantial justice.

PRODUCT BACKGROUND

9. In or about May 17, 2006, a company called Smiths Medical Md, Inc. received clearance via the 510(k) Premarket Notification Program from the Food and Drug Administration (FDA) to market and sell a product called Port-a-Cath II.

10. On or about January 6, 2022, ICU Medical Inc. completed the acquisition of Smith's Medical including the vascular access devices designed and manufactured by Smith's Medical.

11. Defendant's Vascular Access Devices were designed, patented, manufactured, labeled, marketed, sold, and distributed by the Defendant at all relevant times herein.

12. The Port-A-Cath II is one of several varieties of port/catheter systems that has been designed, manufactured, marketed, and sold by Defendant.

13. According to Defendant, the Port-A-Cath II is a totally implantable vascular access device designed to permit repeated access to the venous system for the parenteral delivery of medications, fluids, and nutritional solutions and for the sampling of venous blood.

14. The intended purpose of the Port-A-Cath II is to make it easier to deliver medications directly into the patient's bloodstream. The device is surgically placed completely under the skin and left implanted.

15. The Port-A-Cath II is a system consisting of two primary components: an injection port and a polyurethane catheter which includes additives intended to make it radiopaque.

16. The injection port has a raised center, or "septum," where the needle is inserted for delivery of the medication. The medication is carried from the port into the bloodstream through a small, flexible tube, called a catheter, that is inserted into a blood vessel.

17. The Port-A-Cath II is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.

18. The product's catheter is comprised of a polymeric mixture of polyurethane and a barium sulfate radiopacity agent.

19. Barium sulfate is known to contribute to reduction of the mechanical integrity of polyurethane *in vivo* as the particles of barium sulfate dissociate from the surface of the catheter over time, leaving microfractures and other alterations of the polymeric structure and degrading the mechanical properties of the polyurethane.

20. Researchers have shown that catheter surface degradation in products featuring a radiopaque barium sulfate stripe is concentrated at the locus of the stripe.[1]

21. The design of the product at issue in this case includes a catheter with a stripe containing a stripe with a higher concentration of barium sulfate than the rest of the catheter.

22. According to relevant medical literature, such design is proven to have a higher rate of fracture than catheters without the barium-loaded stripe.

23. The mechanical integrity of a barium sulfate-impregnated polyurethane is affected by the concentration of barium sulfate as well as the heterogeneity of the modified polymer.

[1] See Hecker JF, Scandrett LA. Roughness and thrombogenicity of the outer surfaces of intravascular catheters. *J Biomed Mater Res*. 1985;19(4):381-395. doi:10.1002/jbm.820190404

24. Upon information and belief, Defendant's manufacturing process in designing and constructing the catheter implanted in Plaintiff involved too high a concentration of barium sulfate particles for the polymer formulation, leading to improperly high viscosity of the admixed polyurethane before polymerization and causing improper mixing of barium sulfate particles within the polymer matrix.

25. This defect in the manufacturing process led to a heterogeneous modified polymer which led to an irregular catheter surface replete with fissure, pits and cracks as well as sections of the catheter lumen which contain more than 30% barium sulfate by weight, reducing the catheter strength at those loci.

26. The roughened catheter surface leads to the collection and proliferation of fibrinous blood products, thereby drastically increasing the risk of biofilm, infection, and sepsis.

27. Although the surface degradation and resultant mechanical failure can be reduced or avoided with design modifications (e.g., using a higher grade radiopacity compound and/or encapsulating the admixed polymer within polyurethane), Defendant's elected not to incorporate those design elements into the Port-A-Cath II.

28. At all times relevant, Defendant misrepresented the safety of the Port-A-Cath II system, and negligently designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold the Port-A-Cath II system as safe and effective device to be surgically implanted to provide repeated access to the vascular system for the delivery of medications, intravenous fluids, parenteral nutrition solutions, and blood products.

29. At all times relevant to this action, Defendant knew and had reason to know, that the Port-A-Cath II was not safe for the patients for whom they were prescribed and implanted,

because once implanted the device was prone to fracturing, perforating internal vasculature, and otherwise malfunctioning.

30. At all times relevant to this action, Defendant knew and had reason to know that patients implanted with a Port-A-Cath II port had an increased risk of suffering life threatening injuries, including but not limited to: death; infection; hemorrhage; cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart); cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; and perforations of tissue, vessels and organs, or the need for additional surgeries to remove the defective device.

31. Soon after the Port-A-Cath II was introduced to market, which was years before Plaintiff was implanted with her device, Defendant began receiving large numbers of adverse event reports ("AERs") from health care providers reporting that the Port-A-Cath II was fracturing post-implantation and that fractured pieces were migrating throughout the human body, including to the heart and lungs. Defendant also received large numbers of AERs reporting that Port-A-Cath II was found to have perforated internal vasculature. These failures were often associated with reports of severe patient injuries such as:

a. Hemorrhage;

b. infection/sepsis;

c. cardia/pericardial tamponade;

d. cardiac arrhythmia and other symptoms similar to myocardial infarction;

e. severe and persistent pain;

f. perforations of tissue, vessels and organs; and

g. upon information and belief, even death.

32. In addition to the large number of AERs which were known to Defendant and reflected in publicly accessible databases, there are many recorded device failures and/or injuries related to the Defendant's implantable port products which were concealed from medical professionals and patients through submission to the FDA's controversial Alternative Summary Reporting ("ASR") program.

33. The FDA halted the ASR program after its existence was exposed by a multi-part investigative piece, prompting a widespread outcry from medical professionals and patient advocacy groups.[2]

34. Prior to the discontinuation of the ASR program, Defendant reported numerous episodes of failures of their implanted port/catheter products – including numerous episodes of infection – under the ASR exemption, thereby concealing them from physicians and patients.

35. Defendant was aware or should have been aware that the Port-A-Cath II had a substantially higher failure rate than other similar products on the market, yet Defendant failed to warn consumers of this fact.

36. Defendant also intentionally concealed the severity of complications caused by the Port-A-Cath II and the likelihood of these events occurring.

37. Rather than alter the design of the Port-A-Cath II to make it safer or adequately warn physicians of the dangers associated with the Port-A-Cath II, Defendant continued to actively and aggressively market the Port-A-Cath II as safe, despite their knowledge of numerous reports of infection and associated injuries.

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[2] Christina Jewett, *Hidden Harm: Hidden FDA Reports Detail Harm Caused by Scores of Medical Devices*, Kaiser Health News (Mar. 2019)

38. Moreover, Defendant concealed—and continue to conceal—their knowledge of the Port-A-Cath II's dangerous propensity to precipitate infection. Defendant further concealed their knowledge that the catheter design caused these failures and that these failures cause serious injuries.

39. The conduct of Defendant, as alleged in this Complaint, constitutes willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Plaintiff. Defendant had actual knowledge of the dangers presented by the Port-A-Cath II System, yet consciously failed to act reasonably to:

40. Adequately inform or warn Plaintiff, her prescribing physicians, or the public at large of these dangers;

41. Establish and maintain an adequate quality and post-market surveillance system; or

42. Recall the Port-A-Cath II System from the market.

SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF

43. On or about May 10, 2019, Plaintiff underwent placement of a Smith's Port-A-Cath II, reference number 21-4069-24, lot number 3765354. The device was implanted by Dr. Richard Lowe., South Texas Radiology Imaging Centers Hardy Oak Imaging Center San Antonio, Texas, for the purpose of IVIG therapy for Multiple Sclerosis (MS).

44. Defendant, directly or through their agents, apparent agents, servants, or employees designed, manufactured, marketed, advertised, distributed, and sold the Port-A-Cath II that was implanted in Plaintiff.

45. Defendant manufactured, sold, and/or distributed the Port-A-Cath II to Plaintiff,

through her doctors, to be used for delivery of chemotherapy.

46. On or about September 19, 2022, Plaintiff presented herself to the emergency department at Methodist Hospital Northeast with complaints of abdominal pain and nausea. Blood cultures were drawn on and were positive for VRE bacteremia on September 22, 2023. Plaintiff's medical team determined that the Port-A-Cath II was the source of the infection and that the defective port had to be removed.

47. On October 26, 2022, Plaintiff's defective port was removed by Dr. Joseph A. Corrado at Noble Health Audrain Community Hospital.

48. At all times, the Port-A-Cath II was utilized and implanted in a manner foreseeable to Defendant, as Defendant generated the instructions for use and created procedures for implanting the product.

49. The Port-A-Cath II implanted in Plaintiff was in the same or substantially similar condition as when it left the possession of Defendant and in the condition directed by and expected by Defendant.

50. Plaintiff and her physicians foreseeably used and implanted the Port-A-Cath II and did not misuse or alter the Port-A-Cath II in an unforeseeable manner.

51. Defendant advertised, promoted, marketed, sold, and distributed the Port-A-Cath II as a safe medical device when Defendant knew or should have known the Port-A-Cath II was not safe for its intended purposes and that the product could cause serious medical problems.

52. Defendant had sole access to material facts concerning the defective nature of the Port-A-Cath II product and its propensity to cause serious and dangerous side effects.

53. In reliance on Defendant's representations, Plaintiff's doctors were induced to, and did use the Port-A-Cath II.

54. As a result of having the Port-A-Cath II implanted, Plaintiff has experienced significant mental and physical pain and suffering, has undergone additional surgeries, and has suffered financial or economic loss, including, but to limited to, obligations for medical services and expenses.

55. Defendant's Port-A-Cath II was marketed to the medical community and to patients as a safe, effective, reliable, medical devices implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, and as safer and more effective as compared to the traditional products and procedures for treatment and other competing Vascular Access Devices.

56. The Defendant has marketed and sold the Defendant's Port-A-Cath II to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, direct to consumer advertising, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and/or group purchasing organizations, and include a provision of valuable consideration and benefits to the aforementioned.

57. The injuries, conditions, and complications suffered due to Defendant's Port-A-Cath II include, but are not limited to, infection; nausea; severe and persistent pain.

58. Defendant was negligent toward Plaintiff in the following respects:

a. Defendant failed to design and establish a safe, effective procedure for removal of Port-A-Cath II; therefore, in the event of a failure, injury, or complications it is difficult to safely remove Port-A-Cath II.

b. Defendant provided incomplete, insufficient, and misleading information to physicians in order to increase the number of physicians using Port-A-Cath II for the purpose of increasing their sales. By so doing, Defendant caused the dissemination of inadequate and misleading information to patients, including the Plaintiff.

59. The Port-A-Cath II was utilized and implanted in a manner foreseeable to Defendant.

60. The Port-A-Cath II implanted into Plaintiff was in the same or substantially similar condition as when it left the possession of the Defendant and in the condition directed by the Defendant.

61. At the time of her operation, Plaintiff was not informed of, and had no knowledge of the complaints, known complications and risks associated with Port-A-Cath II, including, but not limited to, the extent of seriousness of the danger of infection.

62. Plaintiff was never informed by Defendant of the defective and dangerous nature of Port-A-Cath II.

63. At the time of her implant, neither Plaintiff nor Plaintiff's physicians were aware of the defective and dangerous condition of the Port-A-Cath II.

64. Plaintiff has suffered and will continue to suffer physical pain and mental anguish.

65. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective product that was implanted in her body.

COUNT I: NEGLIGENCE

66. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

67. The Defendant owed Plaintiff a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, selling and conducting post-market surveillance of the Port-A-Cath II.

68. The Defendant failed to exercise due care under the circumstances and therefore breached this duty by:

a. Failing to properly and thoroughly test the Port-A-Cath II before releasing the device to market, and/or failing to implement feasible safety improvements;

b. Failing to properly and thoroughly analyze the data resulting from any pre-market testing of the Port-A-Cath II;

c. Failing to conduct sufficient post-market testing and surveillance of the Port-A-Cath II;

d. Failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture, inspection, production, advertisement, marketing, promotion, distribution, and/or sale of the Port-A-Cath II;

e. Designing, manufacturing, marketing, advertising, distributing, and selling the Port-A-Cath II to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the Port-A-Cath II and without proper instructions to avoid the harm which could foreseeably occur as a result of using the device;

f. Failing to exercise due care when advertising and promoting the Port-A-Cath II; and

g. Negligently continuing to manufacture, market, advertise, and distribute the Port-A-Cath II after Defendant knew or should have known of its adverse effects.

69. As a direct, actual, and proximate cause of the Defendant's actions, omissions, and misrepresentations, Plaintiff has suffered, and will continue to suffer, severe injuries and complications which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

70. In performing the foregoing acts, omissions, and misrepresentations, Defendant acted grossly negligent, fraudulently, and with malice so as to justify an award of punitive and/or exemplary damages.

COUNT II: STRICT PRODUCTS LIABILITY – DESIGN DEFECT

71. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

72. Defendant supplied, manufactured, sold, distributed and/or otherwise placed into the stream of commerce the Port-A-Cath II implanted into Plaintiff.

73. The Port-A-Cath II implanted in Plaintiff was not reasonably safe for its intended use and was defective with respect to its design.

74. The Port-A-Cath II was in a defective condition and was defective in its design in that when it left the possession of Defendant, it was not safe for its anticipated use and safer, more reasonable alternative designs existed that could have been utilized by Defendant.

75. The Port-A-Cath II was unreasonably dangerous to the user or consumer, taking

into consideration the utility of said product and the risks involved in its use. The foreseeable risks associated with the design of the product were more dangerous than a reasonably prudent consumer such as Plaintiff and/or her physicians would expect when the product was used for its normal and intended purpose.

76. The Port-A-Cath II was expected to and did reach the consumer without substantial change in the condition in which it was supplied, distributed, sold and/or otherwise placed into the stream of commerce.

77. A reasonably prudent medical device manufacturer would not have placed the Port-A-Cath II with its defective design into the stream of commerce.

78. The design defects in the Port-A-Cath II were not known, knowable and/or reasonably apparent to Plaintiff and/or her physician or discoverable upon any reasonable examination.

79. The Port-A-Cath II was used and implanted in the manner in which it was intended to be used and implanted by Defendant pursuant to the instructions for use and the product specifications provided by Defendant.

80. Defendant is strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

81. As a direct and proximate result of the Port-A-Cath II's aforementioned defects, the Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

COUNT III: STRICT PRODUCTS LIABILITY – FAILURE TO WARN

82. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

83. At the time Defendant designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, the device was defective and presented a substantial danger to users of the product when put to its intended and reasonably anticipated use, namely as an implanted port/catheter system to administer intravenous fluids and/or medications. Defendant failed to adequately warn of the device's known or reasonably scientifically knowable dangerous propensities, and further failed to adequately provide instructions on the safe and proper use of the device.

84. Defendant failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Port-A-Cath II; no reasonable health care provider, including Plaintiff's, or patient would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers or the consumers of the device.

85. Defendant knew or should have known at the time they manufactured, labeled, distributed, and sold the Port-A-Cath II that was implanted into Plaintiff that the Port-A-Cath II posed a significant and higher risk than other similar devices of device failure and resulting serious injuries.

86. The warnings, labels, and instructions provided by the Defendant at all times relevant to this action, are and were inaccurate, intentionally misleading, and misinformed and misrepresented the risks and benefits and lack of safety and efficacy associated with the device.

87. The health risks associated with the device as described herein are of such a nature

that ordinary consumers would not have readily recognized the potential harm.

88. The Port-A-Cath II, which was designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold into the stream of commerce by Defendant, was defective at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

89. When Plaintiff was implanted with the device, Defendant failed to provide adequate warnings, instructions, or labels regarding the severity and extent of health risks posed by the device, as discussed herein.

90. Defendant intentionally underreported the number and nature of adverse events associated with fracture of the devices to Plaintiff's health care providers, as well as the FDA.

91. Neither Plaintiff nor her health care providers knew of the substantial danger associated with the intended and foreseeable use of the device as described herein.

92. Plaintiff and her health care providers used the Port-A-Cath II in a normal, customary, intended, and foreseeable manner, namely as a surgically placed device used to make it easier to deliver medications directly into the patient's bloodstream.

93. Upon information and belief, the defective and dangerous condition of the Port-A-Cath II, including the one implanted into Plaintiff, existed at the time they were manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold by Defendant to distributors and/or healthcare professionals or organizations.

94. Upon information and belief, the Port-A-Cath II implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendant.

95. Defendant's lack of sufficient warning and/or instructions was the direct and proximate cause of Plaintiff's serious physical injuries, and economic damages in an amount to be determined at trial. In other words, had Defendant provided adequate warnings, Plaintiff and her physicians would not have used the Port-A-Cath II.

COUNT IV: BREACH OF IMPLIED WARRANTY

96. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

97. Defendant impliedly warranted that the Port-A-Cath II was merchantable and fit for the ordinary purposes for which it was intended.

98. When the Port-A-Cath II was implanted in the Plaintiff, it was being used for the ordinary purposes for which it was intended.

99. The Plaintiff, individually and/or by and through her physician, relied upon Defendant's implied warranties of merchantability in consenting to have the Port-A-Cath II implanted in her.

100. Privity exists between Plaintiff because Plaintiff's physicians acted as Plaintiff's purchasing agents in the subject transaction and/or because Plaintiff was a third-party beneficiary of the subject contract.

101. Plaintiff was the intended consumer of the device when Defendant made the warranties set forth herein, and such warranties were made to benefit Plaintiff as a patient and consumer.

102. Defendant breached these implied warranties of merchantability because the Port-A-Cath II implanted in Plaintiff was neither merchantable nor suited for its intended uses as

warranted in that the device varied from its intended specifications, which included, but are not limited to, variances in the following respects:

a. Defendant's manufacturing process in constructing the catheter of the Port-A-Cath II implanted in Plaintiff involved too high of a concentration of barium sulfate particles for the polymer formulation, which led to improperly high viscosity of the admixed polyurethane before polymerization and causing improper mixing of barium sulfate particles within the polymer matrix;

b. Defendant's knew or should have known barium sulfate is known to contribute to a reduction in the mechanical integrity of the polyurethane in its product, the Port-A-Cath II, as the barium sulfate particles dissociate from the surface of the catheter over time; and

c. These defects led to a heterogenous modified polymer that included microfractures and weakened areas at the location of the higher barium sulfate concentration that ultimately led to the collection and proliferation of blood products, thereby drastically increasing the risk of biofilm, infection, and sepsis.

103. Defendant's breaches of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product, the Port-A-Cath II, into Plaintiff's body, placing said Plaintiff's health and safety in jeopardy.

104. The Port-A-Cath II was sold to Plaintiff's health care providers for implantation in patients, such as Plaintiff.

105. As a direct and proximate result of Defendant's breaches of the aforementioned implied warranties, the Plaintiff was caused and/or in the future will be caused to suffer severe

personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

106. Upon information and belief, Plaintiff's healthcare providers sent notice to Defendant of the adverse event that occurred to Plaintiff and thus, the nonconformity of the Port-A-Cath II, within a reasonable period of time following discovery of the breach of warranty and before suit was filed.

COUNT V: BREACH OF EXPRESS WARRANTY

107. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

108. Defendant through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisement, expressly warranted that the Port-A-Cath II was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous side effects, and was adequately tested and fit for its intended use.

109. The Port-A-Cath II does not conform to the Defendant's express representations because it is not reasonably safe, has numerous serious side effects, and causes severe and permanent injury.

114. Defendant further breached express representations and warranties made to Plaintiff, her physicians and healthcare providers with respect to the Port-A-Cath II implanted in Plaintiff in the following respects:

a. Defendant represented to Plaintiff and her physicians and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among

other ways that the Defendant's Port-A-Cath II was safe, meanwhile Defendant fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Port-A-Cath II;

b. Defendant represented to Plaintiff and her physicians and healthcare providers that the Defendant's Port-A-Cath II was as safe and/or safer than other alternative procedures and devices then on the market, meanwhile Defendant fraudulently concealed information that demonstrated that Port-A-Cath II was not safer than alternative therapies and products available on the market; and

c. Defendant represented to Plaintiff and her physicians and healthcare providers that the Defendant's Port-A-Cath II was more efficacious than other alternative procedures, therapies and/or devices. Meanwhile Defendant fraudulently concealed information, regarding the true efficacy of Port-A-Cath II.

110. At all relevant times, the Port-A-Cath II did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

111. Plaintiff, her physicians, and the medical community reasonably relied upon the Defendant's express warranties for the Port-A-Cath II.

112. Privity exists between Plaintiff because Plaintiff's physicians acted as Plaintiff's purchasing agents in the subject transaction and/or because Plaintiff was a third-party beneficiary of the subject contract.

113. Plaintiff was the intended consumer of the device when Defendant made the warranties set forth herein, and such warranties were made to benefit Plaintiff as a patient and

consumer.

114. Plaintiff was intended consumer of the Port-A-Cath II when Defendant made the warranties set forth herein, and such warranties were made to benefit Plaintiff as a patient and consumer.

115. At all relevant times, the Port-A-Cath II was used on Plaintiff by Plaintiff's physicians for the purpose and in the manner intended by Defendant.

116. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

117. As a direct and proximate result of the breach of Defendant's express warranties, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

118. Upon information and belief, Plaintiff's healthcare providers sent notice to Defendant of the adverse event that occurred to Plaintiff and thus, the nonconformity of the Port-A-Cath II, within a reasonable period of time following discovery of the breach of warranty and before suit was filed.

COUNT VI: FRAUDULENT CONCEALMENT

119. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

120. Defendant engaged in and fraudulently concealed material information with respect

to the Port-A-Cath II in the following respects:

a. Defendant fraudulently withheld and concealed information regarding the substantial risks of using the Port-A-Cath II, including, but not limited to, its heightened propensity to precipitate infection, and cause complications from the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions;

b. Defendant received reports of Port-A-Cath II catheter failures and the nature of these injuries but did not disclose that the frequency of these Port-A-Cath II catheter failures and that the severity of injuries associated with these failures were substantially worse than had been reported;

c. Defendant concealed that it knew of the Port-A-Cath II's dangerous propensity to precipitate infection and was causing complications from causes other than the manner in which the implanting physician implanted the device;

d. Defendant intentionally underreported the number and nature of adverse events associated with the fracture of Port-A-Cath II catheters to physicians (including her own) and the general public (including herself).

e. Defendant utilized the FDA's Alternative Summary Reporting program to report adverse events in order to conceal these reports and prevent Plaintiff and her physicians from discovering the true risks of their Port-A-Cath II catheters.

121. Defendant had a duty to disclose each of the material facts that they fraudulently concealed from Plaintiff and her physicians.

122. Defendant had sole access to material facts concerning the dangers and

unreasonable risks of the Port-A-Cath II.

123. The concealment of information by the Defendant about the risks of the Port-A-Cath II was intentional.

124. The concealment of information about the Port-A-Cath II was made by the Defendant with the intent that Plaintiff's health care providers and Plaintiff rely upon them.

125. Plaintiff and her physicians were unaware of the substantial risks of the Port-A-Cath II which the Defendant concealed from the public, including Plaintiff and her physicians.

126. As a direct and proximate result of the Defendant's actions, omissions and misrepresentations, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

127. The Defendant acted with oppression, fraud, and malice towards Plaintiff, who accordingly requests that the trier of fact, in the exercise of its sound discretion, award additional damages for the sake of example and for the purpose of punishing Defendant for their conduct, in an amount sufficiently large to be an example to others, and to deter this Defendant and others from engaging in similar conduct in the future.

128. Had Defendant not concealed this information, neither Plaintiff's nor her health care providers would have consented to using the Port-A-Cath II placed in Plaintiff.

COUNT VII: TEXAS'S Deceptive Trade Practices-Consumer Protection Act

129. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

130. Plaintiff purchased the Port-A-Cath II, and the product was intended for personal use.

131. The acts and practices engaged in by Defendant as outlined above constitute unlawful, unfair, and/or fraudulent business practices in violation of the Texas Deceptive Trade Practices-Consumer Protection Act, (Texas DPTA), Texas Bus. and Comm. Code §17.41 *et seq.*

132. Defendant engaged in unlawful practices including deception and/or the concealment, suppression, or omission of material facts in connection with the sale, distribution, and/or advertisement of the Port-A-Cath II in violation of. Tex. Bus. and Comm. Code §17.50

133. Defendant further knowingly or recklessly engaged in unfair, unconscionable, deceptive, deliberately misleading, false, and/or fraudulent and deceptive acts and practices, all in violation of the TEXAS DPTA, and as further described herein, which created a likelihood of confusion or misunderstanding on Plaintiff's part with respect to the Port-A-Cath II she purchased, including, but not limited to, failing to adequately disclose the substantial risk of infection and harm the product entailed, given the large number of adverse events Defendant knew or should have been aware of but did not adequately disclose to Plaintiff.

134. Defendant's practices were likely to mislead consumers who acted reasonably to their detriment in purchasing the product without knowledge of the adverse events and substantial risk of infection caused by Defendant's product, which they failed to disclose.

135. Defendant intended for Plaintiff, Plaintiff's physicians, and other consumers to rely on their deceptive practices and representations in order to continue selling and manufacturing the Port-A-Cath II.

136. As a result of Defendant's conduct, Plaintiff suffered economic damages in that the

product purchased was misrepresented to be reasonably safe for use and was worth less than the product Plaintiffs thought they had purchased had Defendant's representations been true.

PRAYER

WHEREFORE, Plaintiff prays for judgment against Defendant as follows:

a. Judgment be entered against Defendant on all causes of action of this Complaint;

b. Plaintiff be awarded her full, fair, and complete recovery for all claims and causes of action relevant to this action;

c. Plaintiff be awarded general damages according to proof at the time of trial;

d. Plaintiff be awarded damages, including past, present, and future, medical expenses according to proof at the time of trial;

e. Plaintiff be awarded costs and attorney's fees in connection with Plaintiff's Texas Deceptive Trade Practices-Consumer Protection Act (DTPA) claim under Tex. Bus. and Comm. Code § 17.41 *et seq.* and Tex. Bus. and Comm. Code § 17.50

f. Awarding pre-judgment and post-judgment interest to the Plaintiff;

g. Awarding the costs and the expenses of this litigation to the Plaintiff;

h. For such other and further relief as the court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

Respectfully submitted,

THE COCHRAN FIRM

/s/ Larry Taylor
Larry Taylor
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ATTORNEY FOR PLAINTIFF

CERTIFICATE OF SERVICE

I hereby certify that on November 11, 2024, I electronically filed the foregoing document with the Clerk of Court using the Court's CM/ECF system. A copy has been served to defendant via CMRRR and to counsel Andrea Roberts Pierson (andrea.pierson@faegredrinker.com), Abbey Hayford (abbey.hayford@faegredrinker.com) Nikki Vega (nvega@prichardyounglp.com) and Eric Scott (escott@prichardyounglp.com) via electronic mail.

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